REMARKS

Reconsideration and withdrawal of the claim rejections are requested in view of the amendments and remarks herein.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-12 and 15 are under consideration in this application. Claims 1, 2, 7 and 8 have been amended and claim 13 has been cancelled. Support for the amended claims is found throughout the specification. Specifically, support for the recitation "under stringent conditions" in claim 1 can be found in the paragraph bridging pages 20 and 21 of the application.

No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

Restriction Requirement

Applicants wish to reiterate their position with respect to the requirement for election of a single nucleotide sequence. While it is appreciated that the Patent Office does not have the resources to examine a varied multitude of sequences in a single application, it is respectfully submitted that, in this instance, that is not the situation.

Contrary to the assertion in the Office Action that "[t]he nucleotide sequence of SEQ ID NOs:1-10 are drawn to DNA compositions of discreet length and function", the sequences represented by SEQ ID NOs:1-10 are members of a single structurally and functionally related genus. In fact, they are all part of the same sequence. SEQ ID NO:1 comprises the complete promoter of the invention, and SEQ ID NOs:2-10 constitute fragments of SEQ ID NO:1. For example, SEQ ID NO:2 corresponds identically to the first 844 nucleotides of SEQ ID NO:1. Likewise, SEQ ID NO:3 corresponds identically to nucleotides 845-1724 of SEQ ID NO:1. Similarly, SEQ ID NO:4 consists of nucleotides 1725-2240 of SEQ ID NO:1; SEQ ID NO:5 consists of nucleotides 2241-2742 of SEQ ID NO:1; SEQ ID NO:6 consists of nucleotides 2743-

3003 of SEQ ID NO:1; SEQ ID NO:7 consists of nucleotides 3064-3330 of SEQ ID NO:1; SEQ ID NO:8 consists of nucleotides 3331-3566 of SEQ ID NO:1; SEQ ID NO:9 consists of nucleotides 3567-4070 of SEQ ID NO:1; and SEQ ID NO:10 consists of nucleotides 4071-4511 of SEQ ID NO:1.

Therefore, if the Examiner has searched and examined SEQ ID NO:1, SEQ ID NOs:2-10 were necessarily included in the exercise. Further, these sequences, fragments of SEQ ID NO:1, are not of discreet function, as is asserted on page 2 of the Office Action; rather, they all have the function of a caryopsis-specific promoter. These sequences simply cannot be considered independent and patentably distinct, as each of SEQ ID NOs:2-10 is found within SEQ ID NO:1. As such, reconsideration and withdrawal of the requirement for restriction of the application to SEQ ID NO:1 are requested.

II. THE REJECTIONS UNDER 35 U.S.C. §112, 1ST PARAGRAPH ARE OVERCOME

The Application Contains Adequate Written Description

Claims 1-13 and 15 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. The rejection is traversed.

As admitted on page 3 of the Office Action, there is clearly written description for the nucleotide sequence of SEQ ID NO:1. The phrase "under stringent conditions" has been added to part (d) of claim 1 to more clearly define how hybridization is to be performed. The section of the specification beginning on page 20, line 23 discusses hybridization and discloses the preferred conditions. There is also a great deal of discussion in the specification (see, for example, the section beginning on page 17, line 15) regarding portions of SEQ ID NO:1 that retain functional activity. The function of the claimed promoter is well-described, as are methods for testing its activity.

The claimed nucleic acid molecule of claim 1 is described functionally and structurally by sequence identifiers, hybridization conditions and percent identity. Hybridization techniques using a known nucleotide sequence (*e.g.* SEQ ID NO: 1) as a probe under stringent conditions were conventional in the art at the time of filing, as were techniques for determining sequence identity. A person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the stringent hybridization conditions and the percent identity limitations set forth in the claim yield structurally similar polynucleotides. Therefore, a representative number of species is disclosed, and claim 1, drawn to a genus of

nucleic acids that hybridize with, or have sequence identity to, a given sequence and have a specified, measurable activity, is adequately described.

It is respectfully requested that the Examiner review Examples 9 and 14 of the USPTO's "Synopsis of Application of Written Description Guidelines". These examples mirror the facts of the instant application with respect to claims reciting hybridization and percent identity to a sequence that is adequately described.

The Claims Are Enabled

Claims 1-13 and 15 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

The application describes how to obtain the promoter of SEQ ID NO:1, how to produce various fragments of SEQ ID NO:1, and how to test the fragments to determine whether they are functional.

There would be no undue experimentation on the part of the skilled artisan to isolate a nucleic acid molecule that that has the nucleotide sequence of SEQ ID NO:1, or a functional portion thereof, or that has approximately 75-99% sequence identity to SEQ ID NO:1. Further, specific guidance is given in the specification regarding how to isolate a nucleic acid molecule that hybridizes under stringent conditions to the aforementioned nucleic acid molecules. As discussed above, claim 1 unambiguously recites the structure of the claimed molecules. In addition, claim 1 contains the functional limitation that the nucleic acid molecule has the function of a caryopsis-specific promoter. The specification provides clear direction for determining the promoter activity (see, for example, Examples 6 and 7 on pages 45-47). Further, procedures for identifying, by structural characteristics, a nucleic acid molecule having approximately 75-99% identity to SEQ ID NO:1 are standard in the art. There is no reason to expect that one of skill in the art could not identify a member of the claimed genus based on its structural and functional characteristics.

The Examiner is respectfully reminded that the standard for enablement precludes undue experimentation, not any experimentation at all. It is well within the skill of one in the art to construct test vectors comprising nucleotide sequences which are a portion of, hybridize under stringent conditions with, or have approximately 75-99% sequence identity to SEQ ID NO:1.

Several references are cited in the Office Action as part of a discussion regarding the state of the art. It is submitted that these references are not relevant to the instant application.

For example, Park et al. (1996) relates to gene silencing in a specific application of a homologous promoter. As is shown in the present application, such problems do not occur in plants transformed with the promoter of the invention, and successful expression under the control of the promoter in caryopses is shown (see Example 8 on page 47 of the specification).

Benfry et al. (1990) is cited by the Examiner to support his view of unreasonable degree of predictability regarding expression patterns of promoters. It is pointed out that within the 10 years between Benfry et al. and the filing of the present application, the methods available to the expert, including transformation efficiency and localization, have been much improved so that a reasonable degree of predictability is obtained, and verification of the predicted promoter activity is not an undue burden to a skilled person.

Also, it is pointed out that the present application is not directed to the 35S promoter, but to the isolation and function of a caryopsis specific promoter. The activity of minimal promoters (e.g. 35S) as mentioned on page 19, line 9, refers to the activity as an enhancer, i.e. an enhancement of the claimed promoter function.

Ellis et al. (1987) describes sequences of the ADH-1 promoter from maize controlling anaerobic regulation. The focus of this publication is to show expression of maize genes in tobacco plants, similar to what is disclosed in the publication of Robert et al. (1989). In this respect, it is pointed out that caryopsis specificity is limited to monocot plants, as dicot plants do not have caryopses. Also, Applicants refer to the section of the specification beginning on page 19, line 7, extensively discussing the aspects of subdomains, cis-, and enhancer elements with respect to the present invention. Also, on page 30, line 10 to page 35, line 11, isolated cis-regulatory DNA elements are disclosed, which have been identified as endosperm or seed specific. As is evident by these points, the references cited in the Office Action do not fairly reflect the state of the art with respect to the currently claimed invention, and do not support an argument of non-enablement.

It is submitted that the claims are in compliance with the first paragraph of §112, and reconsideration and withdrawal of the rejections thereunder are requested.

III. THE REJECTION UNDER 35 U.S.C. §112, 2ND PARAGRAPH IS OVERCOME

Claim 13 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Claim 13 has been cancelled, obviating the rejection. Reconsideration and withdrawal are requested.

IV. THE REJECTIONS UNDER 35 U.S.C. §101 ARE OVERCOME

Claim 13 was rejected under 35 U.S.C. §101 as not being a proper process claim. Claim 13 has been cancelled, obviating the rejection.

Claims 1 and 2 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Claims 1 and 2 have been amended to recite an "isolated" nucleic acid molecule, overcoming the rejection.

In view of the foregoing, reconsideration and withdrawal of the rejections under 35 U.S.C. §101 are requested.

V. THE REJECTIONS UNDER 35 U.S.C. §102 ARE OVERCOME

Claims 1-13 and 15 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Robert et al. The rejection is traversed.

Robert et al. describe a glutenin gene from wheat with tissue-specific expression in tobacco. The promoter sequence used in Robert et al. is not related to the promoter sequences claimed in the present invention, as is evident from the attached sequence comparison, which shows only 48% identity between SEQ ID NO:1 and the sequence referred to in Robert et al., citing Thompson et al. The subject matter of the present application is not the expression of wheat genes in tobacco, but the isolation of a caryopsis specific promoter from wheat coding for starch synthase II, a completely different enzyme. Therefore, Robert et al. can not anticipate or render obvious claims 1-12 and 15.

Claims 1 and 2 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Li et al. The rejection is traversed.

Li et al. have expressed SSII in various plant tissues such as leaves, endosperm, florets, etc. and have found that the highest mRNA expression can be detected in leaves (see Fig. 6). This means that Li et al. have not shown a caryopsis-specific activity. To the contrary, the present inventors have shown caryopsis-specific activity of SEQ ID NO.1. Further, as demonstrated on the attached sequence comparison, the sequence of Li et al. has only 45.9% identity to SEQ ID NO:1, and is clearly out of the scope of the claims.

In addition, Li et al. was published in August, 1999, while the earliest priority date of the instant application corresponds with the filing date, July 6, 2000, of German application DE 100 32 379.0. If necessary, Applicants will provide an English translation of the priority application, confirming that the 5' untranslated region of cDNA encoding a caryopsis-specific class II starch

synthase from wheat was disclosed less than one year after the publication of Li et al. However, for the reasons stated above, it is believed that the claims are not anticipated by Li et al., and that reliance on the disqualification of Li et al. as a proper 102(b) reference will be unnecessary.

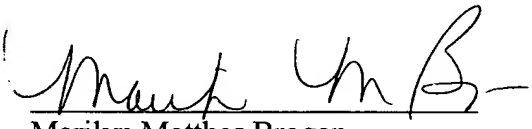
Reconsideration and withdrawal of the rejections under 35 U.S.C. §102 are requested.

CONCLUSION

In view of the remarks and amendments herewith, it is believed that the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By: 

Marilyn Matthes Brogan
Registration No. 31,223
(212) 588-0800